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| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|------------------------|------------------|
| 10/686,138                      | 10/15/2003  | Brian J. Brown       | 03-167US (202.0080001) | 6236             |
| 54953                           | 7590        | 02/18/2010           | EXAMINER               |                  |
| BROOKS, CAMERON & HUEBSCH, PLLC |             |                      | TYSON, MELANIE RUANO   |                  |
| 1221 NICOLLET AVENUE            |             |                      |                        |                  |
| SUITE 500                       |             |                      | ART UNIT               | PAPER NUMBER     |
| MINNEAPOLIS, MN 55403           |             |                      | 3773                   |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/686,138             | BROWN ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | MELANIE TYSON          | 3773                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 July 2009.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9, 12-19 and 22-24 is/are pending in the application.

4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-9, 12-19, and 22 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

This action is in response to the applicant's amendment received 20 July 2009.

The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 10, 11, 20, and 21 remain cancelled. Claims 23 and 24 remain withdrawn from consideration.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-9, 12-19, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification describes the cells are defined by a structural material, and the conductive loop is placed on the structural material that defines the cell. It is unclear as to how the RF markers form loops on only an outside surface of the cells, since the cells do not have a surface. Therefore, the claims do not enable one skilled in the art of how the invention is made with loops on only an outside surface of cells that lack a surface. Furthermore, the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the

applicant failed to disclose loops on only an outside surface of the cells. Therefore, such a limitation is considered new matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 4-9, 13, 14, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson (U.S. Patent No. 6,340,367 B1) and Case et al. (U.S. Publication No. 2004/0167619 - cited on 3/12/07).** Stinson discloses a stent (see entire document) comprising a tubular structure substantially invisible under MRI visualization (for example, see column 1, lines 43-55) having multiple cells including, but not limited to, first and second cells at a first end of the stent facing opposite directions (thus having orthogonal axes generally perpendicular to each other) and third and fourth cells at a second end of the stent facing opposite directions (thus having orthogonal axes generally perpendicular to each other), and RF markers (24) that may form

generally concentric loops of conductive material on only an outside surface of any of the cells in which imaging is desired (for example, see Table 2 which also describes coils may be used to mark the ends of the stent) capable of operating and performing the functions as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made as a matter of design choice to form the loops on first, second, third, and fourth cells facing opposite directions, or any other cells on the stent ends or body, in order to render those portions visible under MRI if so desired. Furthermore, one of ordinary skill in the art would have recognized that marking multiple cells of a stent on both ends would render the stent length even more visible, thus enhancing imaging and accuracy of stent placement. Stinson fails to disclose specifically that the loops may delineate an outer peripheral circumference of the cells.

Case discloses an endoprostheses comprising markers (see entire document). Case teaches the markers may delineate a peripheral circumference of a cell or aperture of an endoprostheses (for example, see Figure 15) in order to provide precise identification of the cell or aperture (for example, see paragraph 52). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form Stinson's markers such that they delineate the peripheral circumference of the cells as taught by Case. Doing so would provide the advantage described above, thus enabling a precise positioning of not only the device, but of also certain cells of the device within a body lumen.

With further respect to claims 9 and 19, Stinson discloses the markers may be crimped, welded, or otherwise permanently attached to the outer surface of the cells, thus are considered to be embedded in the structural material as claimed.

**Claims 2, 3, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. and Case et al. as applied to claims 1 and 13 above, and further view of Doran et al. (U.S. Publication No. 2002/0055770 A1).**

Stinson as modified by Case discloses the claimed invention except for the combination of ceramic struts and polymer connectors. Doran discloses a stent (see entire document) comprising cells. Doran teaches the cells are interconnected by connectors in order to increase flexibility of the stent (for example, see paragraph 83). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the stent of Stinson as modified by Case with connectors as taught by Doran. Doing so would provide a more flexible stent body. Furthermore, Doran teaches the stent and connectors may be made from materials such as ceramics, polymers, and combinations thereof (for example, see paragraph 187). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the struts of ceramic material and the connectors of a polymer material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

**Claims 12 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. and Case et al. as applied to claims 1 and 13 above, and further view of Jackson et al. (U.S. Publication No. 2003/0004563).** Stinson as modified by Case discloses the claimed invention except for a magnetic susceptibility marker. Jackson discloses a tubular structure (see entire document). Jackson teaches connecting magnetic susceptibility markers (such as paramagnetic materials; paragraph 16) that are visible under MRI to the tubular structure. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the stent of Stinson as modified by Case with a magnetic susceptibility marker as taught by Jackson. Doing so would further enable a user to clearly recognize the position of the stent under MRI (for example, see paragraph 16), thus facilitating proper implantation.

### ***Response to Arguments***

Applicant's arguments filed 20 July 2009 have been fully considered but they are not persuasive. The applicant argues that Stinson and Case fail to teach markers located on an outside periphery of the cells. However, since the stent structure is considered the outside surface of the cells and the markers are only on the stent structure, the markers are considered to be located on only an outside surface of the cells as recited in the claims. The applicant then argues that modifying Stinson's markers as taught by Case is improper since doing so would increase foreign body material to Stinson's device, thus changing the principle operation of Stinson's device.

However, Stinson specifically discloses the markers may be positioned to form one or more circumferential rings on the stent and the markers may be looped one or more times about portions of the stent. Therefore, it is the examiner's position that Stinson does not teach away from delineating an outer circumference of two to four cells of the stent with markers forming loops, since such a structure may actually yield less foreign body material than a stent with looped markers on an outer circumference of all or most of the cells of the stent which is within Stinson's disclosed invention.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is

(571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
February 12, 2010

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773